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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/677,419	10/02/2003	Frank Joseph Bova	5853-439	8454

7590 11/23/2005

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EXAMINER
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KISH, JAMES M

ART UNIT	PAPER NUMBER
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3737

DATE MAILED: 11/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b> 10/677,419	<b>Applicant(s)</b> BOVA ET AL.	
	<b>Examiner</b> James Kish	<b>Art Unit</b> 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10/02/03 & 2/09/04 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## DETAILED ACTION

### *Specification*

1. The disclosure is objected to because of the following informalities:

In Paragraphs [0040] and [0041], the word “**build**” should be replaced with **–built–**. See the first sentence of both paragraphs.

Appropriate correction is required.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-8, 10-12 and 15-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Franklin et al.’491 (US Patent No. 6,327,491). Franklin et al.’491 discloses a customized surgical fixture that can be precisely clamped on the patient’s head by matching the contours of cheek bones and forehead, and the contours of the back of the head respectively (column 7, lines 57-60). The device could also be attached to the skull by means of bone anchors (column 7, lines 4-6). The bone anchors have threaded openings for accepting threaded bolts, which would allow for varying the length (column 4, lines 7-9). Furthermore, the fixture

includes a way of mounting an instrument guide onto it. In the preferred embodiment, the mounting base has a flat surface with a central opening. This flat surface is perpendicular to the trajectory. Also, the fixture is created so that the distance between the target point and the mounting base is a pre-determined to be equal to that of the surgical device being used in the surgery (column 5, lines 12-24). In another embodiment, the instrument guide is adjustable (column 7, line 34). An approach to stereotactic surgery according to the invention involving four steps is described in column 3, lines 36-56). Franklin et al.'491 discloses a method for producing the fixture involving scanning the patient and retrieving a three-dimensional image (column 4, lines 18-22), Using this scanned image to design a fixture that will properly fit over the skull (column 4, lines 57-62), and transferring a solid model file of the designed fixture to a rapid prototyping and tooling machine (column 6, lines 46-47).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Franklin et al.'491 in view of Kuth et al.'646 (US Patent No. 5,663,646). Franklin et al.'491 discloses a non-invasive customized surgical fixture. By excluding the use of a

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instrument guide, there is a hole as seen in Figure 8. However, this fixture does not include an option for holding back skin flaps during surgery. Kuth et al.'646 teaches a head antenna to be used during neurosurgery. The device has the capability of holding skin retractors for use during surgery (column 3, lines 40-45). It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the skin retractors of Kuth et al.'646 in the fixture of Franklin et al.'491 to allow surgeons access to a target.

4. Claims 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Franklin et al.'491 in view of Cosman et al.'541 (US Patent No. 6,122,541). Franklin et al.'491 discloses a non-invasive customized surgical fixture. However, the only discussion of markers is during the scanning process. Cosman et al.'541 teaches a frameless stereotactic head band comprising reference markers, which may be optically detectable structures or LED lights (column 10, lines 30-32). It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the optical markers taught by Cosman et al.'541 in the fixture of Franklin et al.'491 to track the orientation of the patient's head and correct for any head movement (column 10, lines 36-38).


***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Kish whose telephone number is 571-272-5554. The examiner can normally be reached on 8:30 - 5:00 ~ Mon. - Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JMK  
Art Unit 3737

  
BRIAN L. CASLER  
SUPERVISORY PATENT EXAMINER  
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